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10/584,192	06/23/2006	Takayuki Oniki	0171-1287PUS1	3847
2292 7590 03/17/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SUTTON, DARRYL C				
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1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/584,192

Applicant(s)

ONIKI ET AL.

Examiner

DARRYL C. SUTTON

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/19/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/CD)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the amendment filed 11/19/2009. New claim 41 has been added.

Applicant's arguments filed 11/19/2009 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 23-40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Oniki et al. (WO 03/030851) in view of Takeda et al. (US 2001/0007652); and the rejection is applicable to new claim 41.

Applicant argues that the polyols of Takeda are not used as the tooth whitening ingredient; the composition of Takeda are applied by brushing; and Takeda fails to teach application of the composition using a special tool. Therefore, Oniki et al. is being is being improperly combined with Takeda et al.

The Examiner disagrees.

As cited in the Non-final office action dated 08/19/2009, Oniki et al. teaches that glycerin and/or propylene glycol are used as the whitening component, see page 4.

Takeda et al. teaches compositions comprised of propylene glycol and/or glycerin and shellac which impart gloss on the teeth; and that shellac changes the optical properties of teeth. Further Takeda et al. clearly teaches that there is no limitation on the usage of the composition, see pages 5 and 6 of Non-final office action; and that the composition can be applied directly to teeth [0019], brushing is only one possible application method. Takeda et al. is referenced as prior art to teach that shellac is a compound which changes the optical properties of teeth, which provides adequate motivation for combining with the prior art of Oniki et al.; no mention is made of the methods of Takeda et al.

Applicant argues that the shellac covers the surface of teeth, thereby smoothing the surface thereof. Accordingly, Takeda's shellac would rapidly turn to a state of precipitation on the surface of the teeth, thereby covering the teeth surface. Thus, in Takeda, the infiltration of polyols would not be attained due to the cover that is generated from precipitated shellac on the tooth surface. Substantial hindsight reconstruction is being used to form the instant invention.

The Examiner disagrees.

The Examiner has not been able to find support for Applicant's allegation that "Takeda's shellac would rapidly turn to a state of precipitation on the surface of the teeth, thereby coving the teeth surface. Thus, in Takeda, the infiltration of polyols would not be attained due to the cover that is generated from precipitated shellac on the tooth surface". Further, Takeda et al. teaches the inclusion of dental disinfectants, such as cetylpyridinium chloride. It would have been reasonably expected that the disinfectant

would be able to reach the surface of the teeth to display their disinfecting activity, and therefore, other components of the composition suggested by combining Oniki et al. and Takeda et al. would also be reasonably expected to reach the surface of the teeth.

Applicants argue that the shellac of Takeda would not penetrate into the teeth, especially into the interdental substance, in the dissolved state.

The Examiner disagrees.

The claims do not contain a limitation that the shellac penetrates into teeth, especially the interdental substance. Further, Applicant has not provided any support for the allegation that the shellac would not penetrate into the teeth.

Applicant argues that one of ordinary skill would not have the proper rationale or reason to combine Oniki et al. and Takeda et al. because the types of compositions being employed, as well as the different actions on teeth.

The Examiner disagrees.

As discussed *supra* and in the Non-final office action, it would have been obvious to combine Oniki et al. and Takeda et al. since Oniki et al. teaches a composition that makes teeth look whiter by causing a whitening component to infiltrate the tooth enamel, thereby changing the optical properties of the enamel, and Takeda et al. teaches compositions comprised of shellac, and that shellac changes the optical properties of teeth, see page 6. Oniki et al. teaches the infiltration of teeth by a whitening agent, i.e. propylene glycol and/or glycerin; it would reasonably be expected that the shellac of Takeda et al. would prevent the whitening agent from leaching out, since as Applicant points out, it forms a cover over the teeth.

Applicant argues that the compositions exhibit unexpected and superior results and points to the results as compared to Comparative Example No. 1.

The Examiner disagrees.

While the instant invention gives superior results over Comparative Example No. 1, the results are not unexpected. As discussed *supra*, the addition of a component, i.e. shellac, which is also taught to change the optical properties of teeth would reasonably be expected to provide superior results over a composition which is not comprised of shellac.

After analyzing, assuming *arguendo* that unexpected results have been shown, the claims would not be commensurate in scope with those findings. In Example 1, Applicant has only used 92% by weight of dipropylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of isostearic acid, not any substance which dissolves in dipropylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer,

hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has not specified the amount of free water; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 2, Applicant has only used 92% by weight of 1,3-dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of isostearic acid, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 3, Applicant has only used a combination of 35% by weight of dibutylene glycol and 60% glycerin, not any ingredient selected from the group

consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of isostearic acid, not any substance which dissolves in dibutylene glycol and glycerin and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 3% by weight of sodium carboxymethylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 4, Applicant has only used a combination of 62% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of isostearic acid, not any

substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 5, Applicant has only used a combination of 92.9% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 0.1% by weight of isostearic acid, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose

and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 6, Applicant has only used a combination of 92% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of 12-hydroxystearic acid, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 7, Applicant has only used a combination of 88% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-

630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 5% by weight of shellac, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 8, Applicant has only used a combination of 55% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 5% by weight of shellac, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty

acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 12% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has used 6% thickening silica; 2% sodium laurate; has used 0.3 citric acid; has used 0.7% sodium citrate; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 9, Applicant has only used a combination of 92% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of t-Bu acrylate/ethyl acrylate/methacrylic acid copolymer, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in

any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 10, Applicant has only used a combination of 92% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of methylmethacrylate/ethyl acrylate/trimethyl-ammonium ethyl methacrylate copolymer, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

In Example 11, Applicant has only used a combination of 92% by weight of dibutylene glycol, not any ingredient selected from the group consisting of isopropanol, butanol, ethylene glycol, polyethylene glycol with an average molecular weight of 190-

630, diethylene glycol, propylene glycol, dipropylene glycol, butylene glycol and glycerin or at not any at least one selected from the group consisting of polyethylene glycol with an average molecular weight of 190-639, butylene glycol and glycerin in any amount or any amount from 50 to 99.5%; has only used 1% by weight of methyl acrylate/methacrylic acid copolymer, not any substance which dissolves in dibutylene glycol and is precipitated by an aqueous solution of calcium chloride or at least two or more selected from C₁₄₋₂₂ higher fatty acids and acrylic polymers or any of the compounds of instant claim 25, 26 33 or 34 in any amount or from any amount from 0.1 to 10%; has only used 6% by weight of hydroxypropylcellulose, not any gelling agent or any one selected from the group of polyacrylic acid, carboxyvinyl polymer, hydroxypropylcellulose, carboxymethylcellulose and salts thereof or in any amount or in any amount from 0.1 to 15%; has only contacted the composition for 1 minute, not for any amount from 1 minute to 120 minutes.

Accordingly, the instant claims are much broader in scope than the compositions of the Examples cited by Applicant.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612